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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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7590

03/22/2002

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,864

Applicant(s)

RIED ET AL.

Examiner

Misook Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001 and 27 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

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DETAILED ACTION

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). *Fixed*

Misnumbered claim 20 and 21^{have} been renumbered 19 and 20.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15 step d and claim 16 steps d and e involve "determining the amount of cancer cells in the sample" and "^{staging} correlating the amount of cancer cells in the sample with a stage of cancer." The specification does not teach what kinds of sample to use, what kind of cancer cells to look for, and what amount of cells is characteristic of a stage of cancer. There are many forms of cancer with many different forms of

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progression, and a large quantity of experimentation is required to correlate any marker with the stages of some particular form of cancer. In the absence of any guidance, it is concluded that undue experimentation would be required to practice this invention as claimed.

Claims 17 and 18 (steps d and e) involve "determining the amount of cancer cells" and "correlated with progression of cancer." The specification does not teach what kinds of sample to use, what kind of cancer cells to look for, and what amount of cells is characteristic of progression of cancer. There are many forms of cancer with many different forms of progression, and a large quantity of experimentation is required to correlate any marker with the stages of some particular form of cancer. In the absence of any guidance, it is concluded that undue experimentation would be required to practice this invention as claimed.

Claims 19 and 20 step d involve "determining the amount of cancer cells in the sample" and "correlating the amount of cancer cells in the sample with the effectiveness of the anti-cancer treatment." The specification does not teach what kinds of sample to use, what kind of cancer cells to look for, and what amount of cells is characteristic of the effectiveness of the anti-cancer treatment. There are many forms of cancer with different degrees with response to a cancer treatment, and a large quantity of experimentation is required to correlate any marker with treatment response of some particular form of cancer. In the absence of any guidance, it is concluded that undue experimentation would be required to practice this invention as claimed.

For the prior art search purpose of this office, the examiner will assume the phrase "obtaining a biological sample containing a cell from a patient diagnosed with cancer" in the claims 15-20 means that the samples are from blood (see the first paragraph of the instant specification) or other bodily fluid. However, this treatment does not relieve applicants of the burden of response to this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15,17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by WO97/38313 (IDS A2). Claims 1-14 are drawn to cancer detection method by enriching circulating epithelial cells and detecting a hybridization pattern with a probe or multiple probes using various conventional detection methods.

WO97/38313 teaches: 1) how to enrich cancer cells from various bodily fluid sources including blood (page 3 lines 1-17, page 6 line 3 to page 18 line 28); 2) how to enrich cancer cells of epithelial origin from blood (abstract and the second paragraph of page 1, the first paragraph of page) by immunomagnetic beads (the second paragraph of page 2), cytokeratin screening, and other methods (page 19, lines 15-17, page 20

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lines 22-29); 3) detecting the hybridization pattern using various conventional detection methods (see page 21 to the first paragraph of page 26) and multiple probes (Example 7). The disclosed examples of probe associated with specific cancer and a genetic marker are PSMA, PSA, and centromeric regions of chromosomes 7, 8, 18 (page 21-22). Further, WO97/38313 teaches methods of determining status and progress of cancer patient, and monitoring efficacy of cancer treatment at page 3 lines 18-26, page 25, lines 19-26, examples 2, 7 and 11.

Thus, claims 1-15, 17, and 19 are anticipated by WO97/38313.

Claims 16, 18, and 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Racila et al (IDS A26).

Racila et al teaches cytometric and immunocytochemical methods (see the Methods section) using various antibodies that forms detectable complexes, that give a good correlation between changes in the level of tumor cells in the blood with status and prognosis of a cancer, and the effectiveness of an anti-cancer treatment (abstract, Table 1, and Fig. 4).

Thus, claims 16, 18, and 20 are anticipated by Racila.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu, Ph. D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa, Ph.D. can be reached on 703-308-3995. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu
March 19, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600
1600